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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,756	04/21/2006	Keiji Shigesada	Q94144	6027
23373 7590 09/16/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
DOE, SHANTA G				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
09/16/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
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### Office Action Summary

**Application No.**

10/576,756

**Applicant(s)**

SHIGESADA ET AL.

**Examiner**

SHANTA G. DOE

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-17 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 18-21 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/26/2010 has been entered.

### ***Response to Arguments***

2. Applicant's arguments with respect to newly amended claims 1 and 12 have been considered but are moot in view of the new ground(s) of rejection. See art rejection below.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1-5 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al (US 6,159,368).

Regarding claim 1, Moring discloses a cartridge ((12) called minicolumn of a column plate for nucleic acid separation and purification which comprises: a cylindrical main body formed of a cylindrical part (12) and a bottom part having an opening; and a nucleic acid-adsorptive porous membrane (8) held on the bottom part, a rim part of the nucleic acid-adsorptive porous membrane being held by a molding material forming the cylindrical part of the cylindrical main body (col. 12 lines 6-7 states that the device is made by injection molding and col. 16 lines 35-42 states that filter element is compressed between the shoulder and rim 16a in a manner effective to secure the filter

element in place and to press the circumferential side edge against the inner surface of the column) which cartridge is produced by: inserting a bottom member and the nucleic acid-adsorptive porous membrane into a cavity of an injection molding die wherein the nucleic acid-adsorptive porous membrane is placed in the bottom member providing the bottom part which is one of two parts that sandwich and hold the nucleic acid-adsorptive porous membrane; and injecting the molding material into the cavity to form the cylindrical part of the cylindrical main body wherein a portion forming the cylindrical part which is the other of the two parts that sandwich and hold the nucleic acid-adsorptive porous membrane is integrated with the bottom member while the nucleic acid-adsorptive porous membrane is sandwiched and held between the cylindrical part and the bottom part (see abs, fig 4-6, col.4 lines 12- 15, 47-49, 65- col. 5 line 5; col. 6 lines 15-20 ,col. 12 lines 6-7; col. 15 – col. 17). Moring fails to specifically disclose that the cylindrical part is integrally formed with the bottom part and nucleic acid-adsorptive porous membrane.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the cylindrical part be integrally formed with the bottom part and nucleic acid-adsorptive porous membrane, since it has been held that forming in one piece an article which has formerly been formed in two (or more) pieces and put together involves only routine skill in the art.

Regarding claim 2, Moring discloses the cartridge for nucleic acid separation and purification according to claim 1, wherein the bottom member further comprises a

cylindrical discharge part (see fig 4&5), the end part of funnel shaped piece of (16)) communicating with the opening of the bottom part.

Regarding claim 3, Moring discloses the cartridge for nucleic acid separation and purification according to claim 1, wherein the rim part of the nucleic acid-adsorptive porous membrane is held and compressed by injection pressure of the molding material forming the cylindrical part of the cylindrical main body (see fig 6, col. 12 lines 6-7, and col. 16 lines 35-42).

Regarding claim 4, Moring discloses the cartridge for nucleic acid separation and purification according to claim 3, wherein the rim part of the nucleic acid-adsorptive porous membrane is compressed until voids in the membrane disappear (see fig 4-6; col. 16 lines 35-56).

Regarding claim 5, Moring discloses the cartridge for nucleic acid separation and purification according to claim 3, wherein the rim part of the nucleic acid-adsorptive porous membrane is compressed. Moring fails to disclose that the membrane is compressed to a thickness of 10% to 70% of an initial thickness.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the membrane be compressed to a thickness of 10 -70 % of an initial thickness, since it has been held that where the general conditions of a

claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

Regarding claim 18, Moring discloses a cartridge (1) for nucleic acid separation and purification comprising a cylindrical body with a first opening (top open end of 12) and a second opening (bottom opening of 12) (see fig. 3 & 6) and having a nucleic acid-adsorptive porous membrane(8a) held in the cylindrical body, in which separation and purification of nucleic acid are conducted by passing a sample solution containing nucleic acid by pressurized gas from the first opening to the second opening to allow the nucleic acid to be adsorbed to the nucleic acid-adsorptive porous membrane, wherein: the cylindrical body comprises: a cylindrical main body having a bottom part supporting the nucleic acid-adsorptive porous membrane (see fig 3 & 6); and a discharge part (16)(see fig 6) connecting the bottom part opening formed in the bottom part and the second opening (see entire document especially fig. 3 , 6 and col. 4 lines 12- 15,47-49, 65-col. 5 line 5; col. 6 lines 15-20, col. 12 lines 6-7; col. 15- col. 17). Moring fails to specifically disclose the thickness of the part forming the second opening of the discharge part.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the thickness of the part forming the second opening of the discharge part be 0.2mm or more, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involve only routine skill in the art.

Regarding claim 19, Moring discloses the cartridge for nucleic acid separation and purification according to claim 18. Moring fails to specifically disclose that a diameter of the second opening is 1.0 mm or more, and an outer diameter of the part forming the second opening is 1.4 mm or more.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the diameter of the second opening be 1.0 mm or more and the outer diameter be 1.4 mm or more, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involve only routine skill in the art.

Regarding claim 20, Moring discloses the cartridge for nucleic acid separation and purification according to claim 18, wherein an angle ( $\alpha$ ) formed by an end face of the discharge part and an outer wall surface of the discharge part is 105° or less (see fig 6 and col. 3 lines 58-60) .

Regarding claim 21, Moring discloses the cartridge for nucleic acid separation and purification according to claim 18, wherein an end face of the discharge part is in a shape of a funnel with a portion closer to the second opening having a larger opening diameter (see fig 3 and col. 3).

***Allowable Subject Matter***

1. Claims 6-11 and 12-17 are allowed.

Regarding claim 6 and its dependent claim, the prior art alone or in combination fails to disclose a method for producing a cartridge for nucleic acid separation and purification: the method comprising a step of placing the nucleic acid absorptive porous membrane on the bottom part provided in the bottom member and placing the bottom member and the membrane in a cavity of an injection molding die; a step of pressing a core pin to the membrane while holding the membrane with a rim part of the membrane protruding from the periphery of an end face of the core pin and closing the injection molding die; a step of injecting a molding material into the cavity forming the cylindrical part of the cylindrical main body and at the same time sandwiching and holding the rim part of the membrane between the molding material and the bottom part and step of removing a casting from the injection molding die.

Regarding 12-17, the prior art fails to disclose the cartridge having a protrusion where in the top part of each protrusion slopes down to the discharged part in a radial direction of the bottom part.

The closest prior art to the applicant invention claimed in claims 6-17 is Moring et al (US 6,159,368).

The Moring reference discloses a cartridge for nucleic acid separation and purification where the cartridge comprises a cylindrical main body formed of a cylindrical part and a bottom part having an opening and a nucleic acid adsorptive porous membrane held on the bottom part wherein the device is made by injection molding (see Moring abs, fig 4-6, col.4 lines 12- 15, 47-49, 65- col. 5 line 5; col. 6 lines 15-20 ,col. 12 lines 6-7; col. 15 – col. 17. However, the reference fails to disclose the specifics of the method by which the device is made and hence the reference fails to disclose the steps of the method as is claimed by the applicant in claim 6 or a cartridge comprising a protrusion wherein the top part of each protrusion slopes down to the discharged part of the cartridge in a radial direction of the bottom part .

2. Claims 22 and 23 are objected to as being dependent upon a rejected base claim (claim 18), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 22, the prior art fails to disclose the device of claim 18 wherein resin hydrophilicity of an end face and an outer wall surface of the discharge part is enhanced.

Regarding claim 23, the prior art fails to disclose the cartridge for nucleic acid separation and purification according to claim 18, wherein at least one lug member for guiding bubbles is provided on an end face of the discharge part.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797